

112TH CONGRESS
2D SESSION

H. R. 6502

To amend title V of the Federal Food, Drug, and Cosmetic Act to provide for extensions of marketing exclusivity periods for drugs in certain combinations of such drugs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 21, 2012

Mr. BILBRAY (for himself, Mrs. MALONEY, and Ms. DELAURO) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend title V of the Federal Food, Drug, and Cosmetic Act to provide for extensions of marketing exclusivity periods for drugs in certain combinations of such drugs, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*

2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Life-Threatening Dis-

5 eases Compassion through Combination Therapy Act of

6 2012”.

1 **SEC. 2. PROMOTING THE DEVELOPMENT OF COMBINA-**
2 **TIONS OF INVESTIGATIONAL NEW DRUGS**
3 **FOR SERIOUS DISEASES.**

4 (a) IN GENERAL.—Subchapter A of chapter 5 of the
5 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351
6 et seq.) is amended by inserting, after section 505, the
7 following new section:

8 **“SEC. 505E. MARKETING EXCLUSIVITY AND PRIORITY RE-**
9 **VIEW FOR SIGNIFICANT DRUG COMBINA-**
10 **TIONS.**

11 “(a) SIGNIFICANT DRUG COMBINATION DESIGNA-
12 TION.—

13 “(1) IN GENERAL.—The Secretary may des-
14 ignate a combination of drugs as a significant drug
15 combination if such combination of drugs—

16 “(A) includes 2 or more drugs (which may
17 include one or more biologics subject to licen-
18 sure under section 351 of the Public Health
19 Service Act) that—

20 “(i) when used in combination, offer
21 the potential to significantly advance treat-
22 ment for a serious or life-threatening dis-
23 ease; and

24 “(ii) in combination, meet the criteria
25 for codevelopment of drug combinations, as
26 specified in the Food and Drug Adminis-

1 tration's guidance document entitled 'Guid-
2 ance for Industry: Codevelopment of Two
3 or More Unmarketed Investigational Drugs
4 for Use in Combination' or a successor
5 document; and

6 “(B) includes at least 2 drugs that, as of
7 the date on which such designation is made, are
8 not approved under section 505 of this Act or
9 licensed under section 351 of the Public Health
10 Service Act.

11 “(2) PURPOSE.—The purpose of the designa-
12 tion under paragraph (1) is to encourage the code-
13 velopment of such drug combinations.

14 “(3) TASK FORCE RECOMMENDATIONS.—In
15 making designations under paragraph (1), the Sec-
16 retary shall take into account the recommendations
17 submitted by the codevelopment task force under
18 section 3(c)(1) of the Life-Threatening Diseases
19 Compassion through Combination Therapy Act of
20 2012.

21 “(4) REQUESTS.—

22 “(A) IN GENERAL.—The manufacturer or
23 sponsor of a drug may request that the Sec-
24 retary determine whether a combination of 2 or
25 more drugs is a significant drug combination.

1 “(B) RESPONSE TO REQUEST.—Not later
2 than 30 days after the submission of the re-
3 quest under subparagraph (A), the Secretary
4 shall review the request and—

5 “(i) if the combination of drugs sub-
6 ject to the request has previously been des-
7 ignated under paragraph (1) and the com-
8 bination of drugs continues to meet the re-
9 quirements for such a designation, the Sec-
10 retary shall provide notice to the person
11 who submitted the request that such com-
12 bination of drugs is a significant drug
13 combination;

14 “(ii) if the combination of drugs sub-
15 ject to the request has not previously been
16 designated under paragraph (1), but the
17 combination of drugs meets the require-
18 ments for such a designation, the Sec-
19 retary shall designate such drug as a sig-
20 nificant drug combination under paragraph
21 (1) and provide notice to the person who
22 submitted the request that such combina-
23 tion of drugs is a significant drug com-
24 bination; or

1 “(iii) if the combination of drugs sub-
2 ject to the request does not meet the re-
3 quirements for designation as a significant
4 drug combination under paragraph (1), the
5 Secretary shall provide notice to the person
6 who submitted the request that such com-
7 bination of drugs is not a significant drug
8 combination.

9 “(C) DEADLINE.—A request for designa-
10 tion under subparagraph (A) shall be made con-
11 currently with, or after, submission of an appli-
12 cation for the investigation of the drug under
13 section 505(i) or section 351(a)(3) of the Public
14 Health Service Act, but not later than the first
15 date on which phase I trials for any of the
16 drugs involved in the drug combination are
17 completed.

18 “(b) LIST OF SIGNIFICANT DRUG COMBINATIONS.—
19 “(1) INITIAL LIST.—Not later than 180 days
20 after the date of enactment of the Life-Threatening
21 Diseases Compassion through Combination Therapy
22 Act of 2012, the Secretary shall develop, and shall
23 publish on the public Web site of the Food and Drug
24 Administration, an initial list of combinations of 2

1 or more drugs that the Secretary has designated as
2 significant drug combinations under subsection (a).

3 “(2) UPDATE.—The Secretary shall revise and
4 update the list under paragraph (1) on an annual
5 basis—

6 “(A) to include additional drug combina-
7 tions that the Secretary has designated as sig-
8 nificant drug combinations under subsection
9 (a); and

10 “(B) to exclude drug combinations which
11 were previously designated as significant drug
12 combinations under subsection (a), but which
13 no longer meet the requirements of subsection
14 (a)(1)(B) (relating to the minimum number of
15 unapproved drugs in a significant drug com-
16 bination).

17 “(c) EXTENSION OF MARKET EXCLUSIVITY.—

18 “(1) IN GENERAL.—If, prior to approval of a
19 drug pursuant to an application submitted under
20 section 505(b), the Secretary designated a signifi-
21 cant drug combination under subsection (a) that in-
22 cludes such drug, then the four- and five-year peri-
23 ods described in subsections (c)(3)(E)(ii) and
24 (j)(5)(F)(ii) of section 505, the three-year periods
25 described in clauses (iii) and (iv) of subsection

1 (c)(3)(E) and clauses (iii) and (iv) of subsection
2 (j)(5)(F) of section 505, or the seven-year period de-
3 scribed in section 527, as applicable, shall be ex-
4 tended by 6 months for such drug.

5 “(2) LIMITATIONS.—Paragraph (1) does not
6 apply to the approval of—

7 “(A) a supplement to an application under
8 section 505(b) for a drug in a designated sig-
9 nificant drug combination, if an extension de-
10 scribed in paragraph (1) is in effect or has ex-
11 pired for the original application (or a prior
12 supplement to such application); or

13 “(B) a subsequent application filed by the
14 same sponsor or manufacturer of a drug in a
15 designated significant drug combination de-
16 scribed in subparagraph (A) (or a licensor,
17 predecessor in interest, or other related entity)
18 for—

19 “(i) a change (not including a modi-
20 fication to the structure of the drug) that
21 results in a new indication, route of admin-
22 istration, dosing schedule, dosage form, de-
23 livery system, delivery device, or strength;
24 or

1 “(ii) a modification to the structure of
2 the drug that does not result in a change
3 in safety or effectiveness.

4 “(d) PRIORITY REVIEW.—If a drug is a drug in a
5 significant drug combination designated under subsection
6 (a), the Secretary shall review and take action on any ap-
7 plication submitted for such drug under section 505(b) or
8 section 351(k) not later than 6 months after receipt by
9 the Secretary of such application.

10 “(e) SIGNIFICANTLY ADVANCE TREATMENT DEFINI-
11 TION.—For purposes of this section, the phrase ‘signifi-
12 cantly advance treatment’ means, with respect to a drug
13 combination—

14 “(1) the drug combination provides for the
15 treatment of one or more life-threatening or other
16 serious diseases or conditions for which no therapy
17 exists; or

18 “(2) if one or more therapies are available for
19 the treatment of such a disease or condition, the
20 drug combination is demonstrated, through clinical
21 investigations to cause one or more improved effects
22 on serious outcomes of the disease or condition that
23 are affected by alternative therapies, such as—

24 “(A) superiority of the drug combination;
25 or

1 “(B) the drug combination minimizes the
2 development of drug resistance,
3 in an active controlled trial assessing an endpoint re-
4 flecting serious morbidity.”.

5 (b) FAST TRACK PRODUCT.—Paragraph (1) of sec-
6 tion 506(a) of the Federal Food, Drug, and Cosmetic Act
7 (21 U.S.C. 356(a)) is amended by inserting after “if it
8 is intended for the treatment of a serious or life-threat-
9 ening condition and it demonstrates the potential to ad-
10 dress unmet medical needs for such a condition” the fol-
11 lowing: “or if such drug is a drug in a significant drug
12 combination designated under section 505E(a)”.

13 **SEC. 3. CODEVELOPMENT TASK FORCE.**

14 (a) ESTABLISHMENT.—Not later than 6 months after
15 the date of enactment of this Act, the Secretary of Health
16 and Human Services shall establish an interagency task
17 force for the purpose of encouraging the codevelopment
18 of drugs in significant drug combinations.

19 (b) MEMBERSHIP.—The membership of the task
20 force under subsection (a) shall include experts on—
21 (1) basic and translational research; and
22 (2) preclinical and clinical drug development re-
23 lated to serious and life-threatening diseases, includ-
24 ing cancer.

1 (c) DUTIES.—The task force under subsection (a)
2 shall have the following duties:

3 (1) RECOMMENDED SIGNIFICANT DRUG COM-
4 BINATION LIST.—

5 (A) INITIAL RECOMMENDATIONS.—The
6 task force shall develop a list of types of drug
7 combinations that the task force recommends
8 that the Secretary designate as significant drug
9 combinations under section 505E of the Fed-
10 eral Food, Drug, and Cosmetic Act.

11 (B) PUBLIC COMMENT.—The task force
12 shall make the list developed under subpara-
13 graph (A) publicly available, and shall provide
14 an opportunity for members of the public to
15 comment on the content of such list.

16 (C) REVISED RECOMMENDATIONS.—Not
17 later than 60 days after making the list publicly
18 available under subparagraph (B), the task
19 force shall revise the list under subparagraph
20 (A) in response to the comments received under
21 subparagraph (B) and shall submit such revised
22 list to the Secretary and the Congress.

23 (D) UPDATES.—On an annual basis, the
24 task force shall submit to the Secretary and the
25 Congress updates to the list under subpara-

1 graph (C), after making such updates publicly
2 available and providing an opportunity for pub-
3 lic comment.

4 (2) POLICY REPORT.—

5 (A) IN GENERAL.—Not later than one year
6 after the date of enactment of this Act, and an-
7 nually thereafter, the task force shall submit to
8 the Secretary and the Congress a report that—

9 (i) identifies—

10 (I) issues that present challenges
11 to the codevelopment of drugs in sig-
12 nificant drug combinations; and

13 (II) opportunities to further sup-
14 port the codevelopment of drugs in
15 significant drug combinations; and

16 (ii) contains recommendations to the
17 Secretary and the Congress on policy
18 changes that could provide additional sup-
19 port for the codevelopment of drugs in sig-
20 nificant drug combinations.

21 (B) PUBLIC COMMENT.—Before submit-
22 ting the report under subparagraph (A), the
23 task force shall make a draft of the report pub-
24 licly available, and shall provide an opportunity

1 for members of the public to comment on such
2 report.

3 (d) APPLICATION OF FACA.—Section 14 of the Fed-
4 eral Advisory Committee Act shall not apply to the dura-
5 tion of the task force under subsection (a).

6 (e) SIGNIFICANT DRUG COMBINATION DEFINED.—
7 For purposes of this section, the term “significant drug
8 combination” means a combination of 2 or more drugs
9 (which may include one or more biologics subject to licen-
10 sure under section 351 of the Public Health Service Act)
11 that—

12 (1) when used in combination, offer the poten-
13 tial to significantly advance treatment for a serious
14 or life-threatening disease;

15 (2) in combination, meet the criteria for code-
16 velopment of drug combinations, as specified in the
17 Food and Drug Administration’s guidance document
18 entitled “Guidance for Industry: Codevelopment of
19 Two or More Unmarketed Investigational Drugs for
20 Use in Combination” or a successor document; and

21 (3) includes at least 2 drugs that are not ap-
22 proved under section 505 of the Federal Food,
23 Drug, and Cosmetic Act (21 U.S.C. 355) or licensed
24 under section 351 of the Public Health Service Act
25 (42 U.S.C. 262).

1 **SEC. 4. STUDY.**

2 (a) IN GENERAL.—The Secretary of Health and
3 Human Services shall conduct a study on the impact of
4 the extensions of exclusivity under section 505E(c) of the
5 Federal Food, Drug, and Cosmetic Act, as added by sec-
6 tion 2, on the development of significant drug combina-
7 tions, as defined in section 3(e).

8 (b) INTERIM FINDINGS.—The Secretary shall—

9 (1) make the interim findings from the study
10 under subsection (a) available to the task force
11 under section 4 and the public; and

12 (2) shall provide an opportunity for the task
13 force and members of the public to make comments
14 on such findings.

15 (c) FINAL FINDINGS.—Not later than 5 years after
16 the date of the enactment of this Act, after providing the
17 opportunity for comment described in subsection (b), the
18 Secretary shall submit the findings of the study under
19 subsection (a) to the Congress.

